

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	
LITIGATION)	MDL No. 1456
)	
)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:)	
)	
<i>United States of America, ex rel. Ven-a-Care</i>)	Subcategory Docket: 06-CV-11337-
<i>of the Florida Keys, Inc. v. Abbott</i>)	PBS
<i>Laboratories, Inc.,</i>)	
CIVIL ACTION NO. 06-CV-11337-PBS)	Hon. Patti B. Saris
)	
<i>United States of America ex rel. Ven-a-Care of</i>)	
<i>the Florida Keys, Inc. v. Dey, Inc., et al.,</i>)	
CIVIL ACTION NO. 05-11084-PBS)	
)	
<i>United States of America ex rel. Ven-a-Care of</i>)	
<i>the Florida Keys, Inc., et al. v. Boehringer</i>)	
<i>Ingelheim Corporation, Inc., et al., CIVIL</i>)	
ACTION NO. 07-10248-PBS)	

UNITED STATES' REPLY TO DEFENDANTS ABBOTT,
DEY AND ROXANE'S COMBINED RESPONSE TO THE UNITED STATES'
STATEMENT OF UNDISPUTED MATERIAL FACTS COMMON TO ALL DEFENDANTS

PRELIMINARY STATEMENT

The United States submits this Reply to defendants' combined response to the United States' Statement of Facts Common to All Defendants to assist the Court by demonstrating that there is no real dispute with respect to the core material facts asserted by the United States in support of its motions for partial summary judgement.¹ The Government is not addressing the responses where defendants have admitted the facts or responded with an assertion of additional fact that, on its face, does not raise a material issue with respect to the truth or accuracy of a statement by the United States.

GENERAL REPLIES

1. Defendants have inappropriately attempted to dispute facts which were asserted by the United States solely for the purpose of disputing facts asserted by *defendants* in support of their motions for summary judgment. The federal rules do not provide for the type of responses stated by defendants, which, in any event, do nothing to resolve any issue in their favor, but only serve to establish that the facts upon which defendants rely for their motions are, indeed, disputed. For example, the United States has not sought summary judgment for any specific amount of damages calculated by its expert. In contrast, defendants have moved for summary judgment on the basis that the United States' damage calculations are inadequate as a matter of law. Hence, the United States included paragraphs 116-169 in its Local Rule 56.1 Statement in order to demonstrate that its damage calculations are thoroughly supported and that defendants are not entitled to judgment as a matter of law on the amount of damages. Defendants' dispute

¹ The United States adopts the abbreviation conventions set forth in footnote 1 of Defendants' Combined Response to the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants.

of those facts demonstrates that their motions for summary judgment on damages should be denied.

2. Defendants' objections that certain of the paragraphs in the United States' Local Rule 56.1 Statement include expert opinion and for that reasons should be disregarded are improper. Each defendant has attacked the damage calculations of the United States' expert, Mark Duggan, Ph.D. in the motions for summary judgment. *See also* Abbott's Daubert motion, Dkts. 6175, 6177. Thus, the United States and its expert must be allowed to respond to those attacks.

3. Defendants purport to dispute numerous of the United States' statements of fact on the ground that the expert opinions relied on by the United States are legal conclusions and that no response is needed. However, the expert opinions are not legal conclusions. Moreover, defendants have cited no authority (and there is none) for the proposition that expert opinions cannot be relied upon in support of, or in opposition to, motions for summary judgment. The cases cited by defendants, *O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) and *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005) hold only that statements of fact offered in support of summary judgment cannot include "conclusory statements" and must be supported by record evidence.

Federal Rule 56 plainly provides that motions for summary judgment may be supported by affidavits which sets out facts and opinions that will be admissible as evidence in this case, as is true for the expert affidavits which accompany the United States' Local Rule 56.1 Statement and the Reply. *See, e.g., Iacobelli Constr., Inc. v. County of Monroe*, 32 F.3d 19, 25 (2d Cir. 1994) ("An affidavit stating the facts upon which the expert's opinion is based satisfies rule

56(e) even if the data supporting the facts is not attached.”). The statements contain no “legal conclusions” in any event. *See, e.g.*, US-SOF No. 120.

4. Defendants do not actually dispute the facts in many of the paragraphs of the United States’ Local Rule 56.1 Statement. Rather, they simply argue that other inferences could be drawn from the undisputed facts. For example, the United States refers to all of the various types of data considered by Professor Duggan as “claims data,” while defendants argue that only certain categories of data should be called “claims data.” The underlying facts are not affected by these semantic distinctions.

5. Defendants’ objections that Dr. Duggan’s calculations are “inaccurate” is a conclusory argument that lacks the specificity required by the Federal Rules – thus making a particularized response by the United States impossible. In any event, conclusory arguments are not sufficient to create a disputed issue. In the same vein, defendants’ arguments that Dr. Duggan’s calculations “lack the proper foundation” are lacking in the specificity needed to assess their merit and should be disregarded.

6. Defendants’ responses repeatedly argue that the variability among the Medicare carriers with respect to how they created pricing arrays used to determine the median prices prevents the calculation of damages unless the United States can assemble perfect evidence proving beyond doubt how the arrays were created. For the reasons set forth in detail in the United States’ Common Reply Memorandum, Section III A and B, defendants have failed to show they are entitled to summary judgment on this issue.

7. Defendants rely heavily on the Bradford 8/28/09 Declaration (Defendants’ Exhibit 405). For the reasons set forth in detail in the United States’ Common Reply Memorandum, Section III A and B, Dr. Bradford’s Declaration is extremely misleading and fails

to demonstrate the existence of any material issues of fact. For example, one of Dr. Bradford's most egregious flaws was that he compared the average amount paid *per claim*, not the average amount paid *per unit*, and failed to account for differences in the number of units in a typical claim (*e.g.*, 219 in New York versus 109 in Pennsylvania). Another egregious flaw is that Dr. Bradford calculated damages using *incomplete* claims data collected directly from the states, and then dropped additional data from his analysis which was not dropped by Dr. Duggan.

8. Defendants have claimed in several responses that the United States has provided no evidence that Dr. Duggan's difference calculation is based on what Medicaid would have reimbursed, *see, e.g.*, Defendants' Response to US-SOF No.128, and that the United States has provided no evidence that the Medicare carriers would have included Dr. Duggan's prices in their arrays, *see, e.g.*, Defendants' Response to US-SOF Nos. 132 and 133. These claims are spurious. *See* United States' Common Reply Memorandum, Section III A.

9. Defendants' repeated reliance upon examples referenced as being contained in Abbott's Motion in Limine (in which Dey and Roxane have not joined) are unspecified, unpersuasive, too vague and general to allow for a response, and will be dealt with in more length in the United States' response to that motion due on October 19, 2009.

In addition to the general consolidated replies set out above, the United States replies to particular arguments or assertions by defendants as follows.

I. THE MEDICARE PART B PROGRAM

A . Medicare Part B Reimbursement Methodology

2. In further support of US-SOF No. 2, the United States respectfully refers the Court to Ex. 3 to the Henderson Common Decl. (MD #6310, Sub. #308) (Declaration of Carolyn Helton) at ¶¶ 9-10.

3. In further support of US-SOF No. 3, the United States respectfully refers the Court to the HHS OIG report, *Medicare Part B - Reimbursement to Providers for Drugs Used in Conjunction with Durable Medical Equipment*," (A-06-92-00079), August 14, 1995 (available at <http://oig.hhs.gov/oas/reports/region6/69200079.htm>) at Appendix D ("Medicare has been covering drugs used with DME for over 20 years."); 54 Fed. Reg. 37220, 37221 (Sept. 7, 1989) ("Payment has also been made for certain drugs and biologicals as part of the durable medical equipment (DME) benefit (section 1861(n) of the Act) and the prosthetic device benefit (section 1861(s)(8) of the Act)").

4. Defendants' objection to the Declaration of Carolyn Helton is baseless. Defendants took her deposition on March 13, 2008, and had every opportunity to question her about Medicare reimbursement. *See* Helton Dec. ¶ 3 ("I have given deposition testimony in this litigation.").

II. THE MEDICAID PROGRAM

A. State Payment Methodologies

25. Defendants' objections to the Knerr Declaration are baseless. The role of Myers and Stauffer in supporting the work of the United States' damages expert, including its work collecting and summarizing information concerning the State Medicaid programs, was fully disclosed months in advance of the close of discovery. Defendants had every opportunity to depose Myers and Stauffer but did not.

26-28. *See* reply at No. 25, above.

29. Defendants misconstrue US-SOF No. 29 and throw out a number of red herrings. The SOF states that currently all Covered States except for Indiana reimburse under a "lower of" methodology in which payment is based, "*at least in part,*" on the lower of EAC, U&C, or the

FUL. (Emphasis added.) The SOF is not intended to address State MAC programs, which are subsequently described in US-SOF No. 32, and the SOF is not made incorrect by the existence of MAC programs. Defendants' assertion that "not all of the Covered States currently have a stated methodology that would pay the lower of EAC, U&C, or FUL (*e.g.*, Arkansas)," is unexplained and unsupported by any citation to evidence, and should be disregarded.

Similarly, defendants' assertion that "the state plan and other material reviewed by Myers and Stauffer do not confirm how the states operated their payment systems in practice," is unexplained and unsupported by any citation to evidence, and should be disregarded. The Declaration of Myers and Stauffer (Amended Ex. 24 to Henderson Common Decl. (MD #6498, Sub. #447)),² explains the lengthy and meticulous process by which the state reimbursement methodologies were prepared and confirmed, including review of State Plan Amendments, sworn deposition testimony and exhibits, and interviews with state Medicaid agency personnel.

To corroborate what should be an obvious proposition, in states employing a lower of reimbursement methodology, state claims-level data confirms claims are in fact paid on the basis of EAC when the EAC is lower than a FUL or a state MAC. (*See, e.g.* Henderson Reply Exhibit 91 (Declaration of Suzane Graydon), ¶¶ 4 - 7); Henderson Reply Exhibit 90 (Declaration of Mark Duggan), ¶¶ 12 -13).

Defendants' remaining objections to US-SOF No. 29 are legal arguments which do not warrant a reply. Furthermore, see reply at No. 25, above.

² On September 10, 2009, the United States filed an amended Exhibit 24 to the Henderson Common Declaration, consisting of the identical Myers and Stauffer declaration that was filed with the Government's original papers, except that certain exhibits were corrected (so that, for example, State Medicaid reimbursement summaries appear in color, rather than in black-and-white font).

30. The summaries of state reimbursement methodologies that are Attachment 1 to the Myers and Stauffer Declaration make very clear that the “AWP” and “WAC” referred to in US-SOF No. 30 are intended to refer to the AWP and WACs published in the compendia. All of the Covered States have used the published compendia AWP and/or WACs to determine their EACs. Given the subject of these lawsuits, defendants cannot reasonably claim confusion about this. *See also* reply at No. 25, above.

31. Regarding the first sentence of defendants’ response, see the reply at No. 29, above. The remainder of defendants’ response presents no genuine dispute that is material to the issues in the summary judgment motions. Thus, defendants’ statement that “many states utilized alternative payment methodologies during some parts of the relevant time period that are not apparent in their state plans (*see* Roxane SOF Nos. 269-79),” does not present any evidence that creates a genuine dispute that “[d]uring the period 1991 to the present, only six Covered States have deviated from the [“lower of”] methodology described in paragraph 29 above.” US-SOF No. 31. For example, Roxane’s SOF No. 270 (referenced in defendants’ response) states that “in Florida, an erroneous computer programming change caused the State Medicaid program to unintentionally remove its WAC-based EAC formula from its reimbursement logic.” This undisputed fact (which is summarized in the Myers and Stauffer summary for Florida) does not contradict the fact that Florida, throughout that time period, used a “lower of” methodology that included the use of AWP to determine EAC. *See* Attachment A to Decl. of Myers and Stauffer (Amended Ex. 24 to Henderson Common Decl. (MD #6498, Sub. #447) (Florida summary). Similarly, defendants’ assertion concerning Hawaii’s reimbursement for drugs where the FUL was higher than the state MAC, does not contradict the statement of US-SOF No. 31 that Hawaii followed the basic “lower of” methodology described in paragraph 29. (Furthermore, as the

United States has already responded, this feature of the Hawaii methodology (which is also described in the Myers and Stauffer summary) is consistent with Hawaii's governing regulations (*see* United States' Response to the Roxane Defendants' Statement of Undisputed Material Facts in Support of Motion for Partial Summary Judgment (MD #2607, Sub. #300) at No. 270, and Haw. Admin. Rules § 17-1739.1-11(a)(2)).

The United States acknowledges that, of the tens of millions of Medicaid reimbursements made during the time period at issue, there may be some anomalies in which a claim was not adjudicated in perfect conformance with the "lower of" algorithm. (*See* Roxane SOF No. 271 (citing *Massachusetts v. Mylan Labs.*, No. 03-11865, 2008 WL 5650859, at *4 (D. Mass. Dec. 23, 2008) ("[i]n certain cases, [Massachusetts] reimbursement exceeded the EAC and the FUL.")). These anomalies, however, are at most relevant to damages and are immaterial to the issue of liability.

With regard to the testimony of Georgia's 30(b)(6) deponent concerning compounded drugs, this is immaterial because the United States has not calculated damages for compounded drugs in Georgia. A compound drug claim in Georgia lists the NDC as "00000000888," populates the "drug name" field with the actual NDC and sets the value of the "drug compound" field to "Y." The United States' damages expert analyzed only claims with NDCs matching those in the complaints and did not use the "drug name" field in the filtering of drug claims, and therefore no compound claims were included in the determination of damages. *See also* reply at No. 25, above; Henderson Reply Exhibit 90, ¶ 14.

32. The United States agrees that, for certain specified periods, as clearly shown in the Myers and Stauffer summaries, the Arkansas and Massachusetts' reimbursement methodologies provided for payment at the lower of the Usual and Customary amount or the FUL or SMAC, if

there was one, and otherwise at the lower of the EAC or Usual and Customary. With regard to Georgia, defendants may be referring to the evidence concerning compounded drugs, which is addressed in response to No. 31 above. Otherwise defendants' response is incorrect and unsupported. With regard to Washington, defendants' response is incorrect and unsupported. *See also* reply at No. 25 above.

33. The United States agrees with defendants' observation that the Knerr Declaration indicates that 29 States (not 25) have used the DOJ Prices as part of their reimbursement methodology. Paragraph 33 should therefore read, "Twenty-nine Covered States add to their "lower of" algorithm. . . ." *See also* Reply at No. 25, above.

34. As demonstrated by Attachment A to the Knerr Declaration (Henderson Common Ex. 24), the statement in US-SOF No. 34 is equally applicable to the entire time period relevant to these cases, save only for the fact that a few States have switched among the three compendia. Defendants' "dispute" is not genuine. *See also* reply at No. 25, above.

35. Defendants' "disputes" are neither genuine nor material, as they generally do not address the specific facts stated in SOF No. 36-85, but make other argument. With regard to defendants' contention that there are "instances where states did not actually operate their payment systems consistent with their state plans," this too does not establish a genuine dispute because SOF Nos. 36-84 do not purport to describe the extent to which states operated their payment systems consistent with their state plans, but rather describe the state reimbursement methodologies used by each state. *See also* reply at No. 25, above.

B. State Claims To the Federal Government For Federal Medicaid Monies

85. Defendants' assertion that the proffered evidence does not support the statement that states provide estimates of drug costs is incorrect. The Declaration of Kristin A. Fan

(Henderson Common Ex. 25) states, “Along with the overall funding request, the state will provide estimates of various types service, including drug costs. *See* Exhibit 1 at p. 2 (Form 37.3) at ln.7.” Line 7 of the CMS Form 37.3 is a line item in the Medicaid Program Budget Report for “Prescribed Drugs.” This evidence directly supports the SOF. Defendants’ other assertions are erroneous and immaterial.

Defendants’ objections to the Fan Declaration are baseless. The fact that a party has not deposed a witness does not render the witness’s declaration inadmissible. Moreover, information concerning the pertinent CMS forms, and the identities of CMS officials knowledgeable about the procedures and practices of states’ claims for federal Medicaid monies, was fully disclosed by the United States in supplemental initial disclosures served upon defendants on October 10, 2007. *See* Fan Decl. ¶ 3. Defendants deposed CMS officials on these subjects for two days on December 17-18, 2007, and had every opportunity to ask, and did ask, about the subjects set forth in the Fan declaration.

91. Defendants’ “qualifications” are immaterial. *See also* Reply at No. 85, above.

IV. CONFIDENTIALITY OF AMP AND URA INFORMATION

97. The United States agrees with defendants’ statement that 42 U.S.C. § 1396r-8(a)(1) requires a pharmaceutical manufacturer to enter into a Medicaid Rebate Agreement as a precondition to that manufacturer’s drugs being reimbursed by state Medicaid programs.

V. DAMAGES

A. Medicaid Data

117. Defendants’ claim that Dr. Duggan should have analyzed the complete state claims data is argument. The single example of a difference between the calculations of the expert hired by Dey and the calculations of the United States’ expert is unsound and

unpersuasive, and at best, shows that genuine issues remain on the damage calculations (as to which the United States has not sought summary judgment).

119. The United States incorporates its Common Reply Memorandum, Section III B. which explains why Figure 3 to the Bradford Declaration is misleading because Dr. Bradford used incomplete data and also dropped claims from his analysis which were not dropped by Dr. Duggan. Thus, the comparison is useless. Moreover, although defendants dispute implications drawn from these facts, in the context of defendants' summary judgment motions, those implications are drawn in favor of the United States.

120. The United States also incorporates its reply to paragraph 118. Additionally, nothing in statement US- SOF 120 constitutes a legal conclusion. Moreover, although defendants argue against the inferences to be drawn from these facts, in the context of defendants' motion for summary judgment, those inferences are drawn in favor of the United States.

B. Medicare Data

124. The references cited by defendants fail to provide any support for defendants' disputing that Medicare carriers consistently followed statutory mandates or regulations. Although there may have been variations in the details of the actual implementation, the evidence is clear that the carriers followed statutory or regulatory mandates. The cited basis for defendants' dispute, Dey SOF 175, does not contradict this statement. It simply adds information. Defendants' reliance on Dey SOF 176 is also misplaced as demonstrated by the United States' response thereto which states as follows:

The United States disputes the second sentence of Dey SOF #176 as unsupported by evidence. Responding further, it appears that the surveys contemplated by the regulations would not have provided a workable basis of reimbursement due to the expense of conducting reliable nation-wide surveys for all covered drugs on

an on-going basis and the inability of such surveys to provide updated prices in a dynamic market.

C. Damages Analysis

132. Defendants are incorrect in stating that “the United States has provided no evidence that the Medicare carriers would in fact choose to include Dr. Duggan’s prices in their arrays.” The United States incorporates by reference its Common Reply Memorandum, Section III B.

135. The materials demonstrating the use of the arrays were produced to defendants in connection with expert witness discovery.

D. Extrapolation

136. Defendants’ assertion that Dr. Duggan “needed” to use the state level claims data should be disregarded because it is unsupported. The United States additionally incorporates its reply at number 132, above.

137. Defendants have not explained the significance, if any, of the fact that aggregate data does not contain information about the basis for payment. The United States reasserts and incorporates its replies at numbers 132 and 136, above.

1. Medicaid Extrapolation

138. The United States reasserts and incorporates its replies at numbers 132, 133 and 136, above.

139. It is immaterial that the aggregate level data does not allow the user to determine the payment basis because of the “lesser of” formula. The United States reasserts and incorporates its replies at numbers 132, 133 and 136, above.

140 - 148. The United States reasserts and incorporates its reply at number 136, above, which explains why the calculations of Dey’s expert are extremely misleading.

a. Intra-State Extrapolation

153 - 153a. The United States reasserts and incorporates its reply at 136, above, which explains why the calculations of Dey's expert are extremely misleading.

b. Inter-State Extrapolation

154. Defendants do not in any way dispute the second sentence of this paragraph which makes clear that Dr. Duggan did not extrapolate to any state or time period for which he did not have data.

2. Medicare Extrapolation

157. The United States reasserts and incorporates its replies at numbers 132 to 133, above.

158. The United States reasserts and incorporates its replies at numbers 132 to 133, above. The United States incorporates by reference its Common Reply Memorandum, Section III B. Responding further, Dr. Duggan was being neither liberal nor conservative in calculating damages arising from the inflated AWP's of the NovaPlus products. Rather, he was applying the mandate of the False Claims Act providing for damages "caused by" the offending conduct. Had Roxane reported truthful AWP's for the NovaPlus products, Medicare spending for those products would have been substantially less. The FCA does not require, as a requisite to liability or damages, that defendants' products have been used by the government program that was victimized.

3. Part B Claims for Abbott Analysis

168. Defendants' reference to unspecified exceptions is vague, unsupported by any record support, and should be disregarded.

169. The United States reasserts and incorporates its reply at No. 166, above.

Respectfully submitted,

For the United States of America,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above “UNITED STATES’ REPLY TO DEFENDANTS ABBOTT, DEY AND ROXANE’S COMBINED RESPONSE TO THE UNITED STATES’ STATEMENT OF UNDISPUTED MATERIAL FACTS COMMON TO ALL DEFENDANTS” to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott
JUSTIN DRAYCOTT
Trial Attorney

Dated: Sept. 22, 2009